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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/774,935	02/09/2004	Nadja Jungmann	17350	8627
23389 7590 12/23/2008 SCULLY SCOTT MURPHY & PRESSER, PC 400 GARDEN CITY PLAZA SUITE 300 GARDEN CITY, NY 11530			EXAMINER HUI, SAN MING R	
			ART UNIT 1617	PAPER NUMBER
			MAIL DATE 12/23/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary****Application No.**

10/774,935

**Applicant(s)**

JUNGMANN ET AL.

**Examiner**

San-ming Hui

**Art Unit**

1617

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 September 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-946)
- 3) ☐ Information Disclosure Statement(s) (PTO/SG/US)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 17, 2008 has been entered.

Applicant's amendments filed June 10, 2008 have been entered.

Claims 1-10 are pending.

The outstanding rejection under 35 USC 102(b) is withdrawn in view of the amendments filed June 10, 2008.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The limitation "free of ... carrier materials"

recited in claim 1 is not supported by the originally filed specification nor originally filed claims. Applicant is required to cancel the new matter.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,458,387 ('387) in view of JP07096166 A (herein after referred as '166, the reference is from the IDS filed 2/9/2004), also provided is the machine translation of '166's detailed description.

'387 teaches the use of microspheres for various purposes such as drug delivery and cosmetics (See col. 29, lines 10-12). '387 also teaches the use of microsphere to deliver various actives. '387 also teaches the use of Eudragit E100 as the coating polymer for forming the microspheres (See col. 36, Example 8 for example) and the pH of the resulting polymer solution is at pH 6.5. '387 teaches the protein component can be a therapeutic protein (col. 3, lines 51-52).

'387 does not expressly teach the microspheres would be degraded in the pH of the skin as 5.0 to 6.0. '387 does not expressly teach the molecular weight of the polymer employed.

'166 teaches microcapsules with the same copolymer (i.e., 2-dimethylaminoethyl methacrylate/methyl methacrylate/n-butyl methacrylate polymer) as useful in cosmetic product (See the abstract, paragraph [0035]). Various cosmetic ingredients such as vitamin C can be added [see paragraph 0022]). The microcapsules are designed being dissolved in the skin pH in the range of 4.5-6.5 (See paragraph [0048]).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the microspheres of '387 in cosmetic composition. It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the polymer herein claimed with the herein claimed MW.

One of ordinary skill in the art would have been motivated to employ the microspheres of '387 in cosmetic composition since it is known to be useful in cosmetic preparation. Cosmetics product employing the herein claimed polymer, i.e., Eudragit E100, is well-known to be dissolved in the skin pH as taught in '166. Furthermore, the optimization of the copolymer MW is considered within the purview of skilled artisan since changing the molecular weight would change the viscosity, solubility of the polymer. Absent evidence to the contrary, such formulation process is considered routine to one of ordinary skill in the art.

### ***Response to Arguments***

Applicant's arguments filed June 10, 2008 averring the cited prior art's failure to exclude carrier material (carrier protein) have been fully considered but they are not persuasive. The examiner notes that not only carrier protein can be incorporated into

the microspheres, but also the therapeutic protein. Therefore, processing the teachings of '387, one of ordinary skill in the art would optimize the components of the cited prior art and arrive at the instant composition.

Applicant's arguments filed June 10, 2008 averring the failure of '166 to teach a non-porous composition have been considered, but are not found persuasive. The purpose of citing '166 is mainly to point out that the herein claimed copolymer (i.e., 2-dimethylaminoethyl methacrylate/methyl methacrylate/n-butyl methacrylate colymer), which is also used in '387 can be dissolved in pH 4.5-6.5. In addition, incorporating active agents into microspheres are well-known in the art (See both cited prior art). Therefore, processing the teachings of the teachings of the cited prior art, one of skilled artisan would employ the herein claimed components in forming the microspheres having the herein claimed properties and actives.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (571) 272-0626. The examiner can normally be reached on Mon - Fri from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

San-ming Hui  
Primary Examiner  
Art Unit 1617

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